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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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[REDACTED] EXAMINER

MEHTA, ASHWIN D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1638 | [REDACTED] |

DATE MAILED: 03/12/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/490,884 | CARRIGAN, LORI LISA |
| | Examiner | Art Unit |
| | Ashwin Mehta | 1638 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 December 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-43 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 1-8,21,23-27 and 40 is/are allowed.
- 6) Claim(s) 9-20,22,28-39,41-43 and 47-49 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejection of claims 14, 17, 33, 36, 41, 43, 45, and 46 under the judicially created doctrine of obviousness-type double patenting is withdrawn, in light of the claim amendments and cancellations.
3. The rejection of claims 3, 5, 14, 22, 33, 40-46, 50, and 51 under 35 U.S.C. 112, 2nd paragraph, is withdrawn in light of the claim amendments and cancellations.
4. The rejection of claims 18-20 and 47-49 under 35 U.S.C. 112, 1st paragraph, for lack of enablement is withdrawn, in light of the claim amendments.

Claim Rejections - 35 USC § 112

5. Claims 22, 30-33, and 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 22: the recitation “said plant has essentially the same morphology and physiology of inbred maize line PH51H other than the trait of male sterility” renders the claim indefinite. It is not clear what is meant by “essentially the same.” The claim indicates that if the

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plant did not have the male sterility trait, it still would only be “essentially the same” as PH51H. It is not clear if plants that lack one or a few properties of PH51H are encompassed by “essentially the same.” If the plants are to have all of the same properties, the specification does not define how the genome may be changed while still yielding a plant that has the same properties as PH51H. It is not clear what plant is being referred to, as a plant that is different from PH51H in any way is not the same plant, as it would not have all of the same morphological and physiological traits. In the paper filed 13 December 2002, Applicant supplies a definition of “essentially derived variety” (response, Appendix C). This definition indicates that an essentially derived variety is distinct and predominantly derived from a protected initial variety, while retaining the essential characteristics of that initial variety. The definition supplied by Applicant also indicates that “essentially derived variety” was introduced to the 1991 Act of the UPOV Convention and was meant to “fill the gap” between Plant Breeder’s Rights and patents. However, the USPTO is not subject to UPOV Convention rules, as Article 35(2) of the 1991 UPOV Convention Act ensures that the United States adheres to its patent system. It is also not clear what the “essential characteristics” of the variety of the instant invention are. It is not clear what differentiates “essential characteristics” from non-essential characteristics.

In claim 30: the recitation “substantially the same” in line 4 renders the claim indefinite. It is not clear what differentiates a plant that is substantially the same as PH51H from one that is the same. The metes and bounds of the claim are not clear.

In claim 33: the recitation “pedigree of said PH51H-progeny maize plant is within 2 or less crosses” renders the claim indefinite. A pedigree is a family tree. It is not clear what is

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meant by a pedigree being within 2 or less crosses to a plant. There is also insufficient antecedent basis for the recitation "the pedigree".

In claim 47: the recitation "essentially unchanged" renders the claim indefinite. Similar to claim 22 above, it is not clear when a plant is considered "unchanged" as opposed to "essentially unchanged," since plants that express different properties are not the same plant.

6. Claims 9-20, 28-39, 41-43, and 47-49 remain and amended claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 26 August 2002 under item 10. Applicant traverses the rejection in the paper filed 13 December 2002. Applicant's arguments were fully considered but were not found persuasive.

Applicant first notes that a claim to an F1 hybrid made with a deposited inbred was expressly acknowledged by the U.S. Supreme Court in *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.* (response, page 8, 4th full paragraph). However, the issue before the court in that case concerned matters under 35 U.S.C. 101, not written description. Applicant argues that F1 plants would have essentially the same genetic markers as the deposited PH51H, and that it is well known to anyone skilled in the art that a hybrid has a genome with one set of alleles from each inbred, and that the genetic profile exhibited in the deposit would be exhibited in the inbred (response, paragraph bridging pages 8-9). However, no information is described about the genetic markers of the deposited PH51H seed. In the absence of that information, one would not

be able to identify an F1 hybrid based only on genetic markers. Further, the hybrid would also exhibit the genetic profile of the other parent, as well, and no description is at all is provided about the other parent. Applicant argues that SSR and RFLP techniques can be used to analyze F1 hybrids and determine if one of its parents is PH51H, and cite Berry et al. for discussing the probability of identifying the parents of a hybrid using SSR data when neither parent is known (response, paragraph bridging pages 8-9). However, Applicants have not described any SSR data for PH51H or the claimed progeny lines, or RFLP or any other molecular markers that are unique to PH51H.

Applicant argues that because of the linked genes fixed in PH51H, one can cross PH51H with another line, select a plant expressing at least 2 PH51H traits and a trait from the other plant line (response, page 9, 2nd full paragraph). However, the other parent could also express some of the same traits as PH51H and pass it on to the progeny. Further, the traits inherited from the other parent are not known, since the description of the other parent is not provided.

Applicant argues that the reason for using traits as a means of description is because it is technically impossible to sequence the entire genome of a specific variety. Applicant continues, drawing analogy to *Ex Parte Tanksley*, in which the Examiner desired that claims recite sequence data in order to better characterize a cDNA and facilitate a prior art search. The Board treated the written description rejection as a rejection under 112 2nd paragraph and held that the Examiner may not dictate the literal terms of claims for the stated purpose of facilitating a prior art search (response, page 10, 2nd full paragraph and the paragraph bridging pages 10-11). However, the situation in *Ex Parte Tanksley* is not analogous. Applicant is not being required to define or describe the claimed subject matter in any particular manner. Rather, here Applicant

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has not sufficiently described any descendent of PH51H in any manner. Applicant argues that F1 progeny have half the genetic material of PH51H, but do not describe how one would identify that material. Further, the F1 also has half of the genetic material of the other, unknown, parent plant. As discussed above, no molecular markers that are unique to PH51H have been described. The morphological and physiological traits are not described for any PH51H descendent to the extent that it would distinguish plants encompassed by the claims from those that are not. Two traits, which would also be displayed by many other corn plants, do not comprise a distinguishing characteristic. No descendent of PH51H would express all of its morphological and physiological traits, unless it is a progeny of a self-cross.

Applicant continues, arguing that amended claims 17 and 33 limit the progeny covered to those within two outcrosses from PH51H, and claims 36 and 41 are limited to one cross away from PH51H. Applicant argues that to those of ordinary skill in the art, this indicates that a line that is fewer crosses away from a starting line will be, as a whole, more highly related to the starting line, and the work of the original breeder in developing the starting line will be retained in the closely related progeny (response, page 11, 1st full paragraph). However, the progeny will also retain the material inherited from the other plants involved in the crosses, which are not described by the specification. The progeny plants would be closely related to the other, unknown parents and ancestors as well. Further, the progeny of claims 17, 33, 36, and 41 are not limited to those within two or one outcrosses from PH51H. Claim 17 for example, limits the method that produces the progeny to comprise 2 or less crosses to a plant that is not PH51H, or to comprise 2 or less crosses to a plant that has PH51H as a parent. For the latter choice, nothing is mentioned about the number of crosses to plants that do not have PH51H as a parent.

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Applicant also argues that it is standard practice within the plant breeding industry for licensors of inbred maize lines to retain a royalty from lines developed through the use of their inbreds, and that this provides evidence that those of ordinary skill in the art of plant breeding describe progeny in terms of pedigree (response, page 11, 1st full paragraph). However, licensors pay royalties to use the licensed inbred, not the product progeny.

Applicant also argues that the mere fact that progeny are not created fails to preclude their patentability, and possession can be shown by describing distinguishing characteristics (response, paragraph bridging pages 11-12). However, only one of the claims indicates that only 2 of the listed traits need to be expressed, and those listed traits are expressed by other plants. The presence of those 2 traits themselves does not distinguish the claimed plants from other plants that express them. Applicants argue that pedigree is a distinguishing characteristic that is in compliance with written description guidelines (response, paragraph bridging pages 11-12). However, a pedigree does not describe the morphological and physiological traits of an organism, especially when all of the ancestors of an organism are not described. Further, it is not clear how a plant that is twenty generations removed from PH51H is described by it.

Applicant argues that the genetics of PH51H is described by the ATCC deposit of its seed, and by limiting the progeny to 2 or less outcrosses, the concern that the progeny are only distantly related to PH51H is addressed (response, page 12, 1st full paragraph). However, the deposit only describes PH51H. It does not describe the morphological and physiological traits of any other plant. Further, all of the claimed plants are not limited to 2 or less outcrosses.

Applicant attempts to draw analogy to *Enzo vs. Gen-Probe, U.S. State of Court of Appeals for the Federal Circuit*, for indicating that there are hundreds of subsequences of a deposited

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sequence which may also meet a claimed hybridization ratio, and for indicating that a deposited sequence is described by virtue of its having been deposited, and that various subsequences, mutations, and mixtures of those sequences are also described, and hold that question as an issue of fact (response, page 12, 1st full paragraph). However, the issue in *Enzo* and the instant rejection is not analogous. The hundreds of subsequences that may meet the claimed invention discussed in *Enzo*, and its various subsequences, mutations and mixtures, must still have the properties of the deposited sequence, not other properties or just a portion of the properties. If the subsequences, mutations and mixtures did not have the same properties, they would not have any relation to the deposited sequence. Applicant continues the analogy to *Enzo*, arguing that the issue of whether progeny as now claimed satisfies the issue of written description is also an issue of fact. Applicant argues that one of ordinary skill would know if PH51H were utilized in a breeding program by looking at the breeding records, and that routine molecular techniques can be used to verify whether PH51H is within the pedigree of a line (response, page 12, 2nd full paragraph). In the instant rejection, the progeny do not express all of the morphological and physiological traits of PH51H, unless it is a product of a self-cross. Further, determination that PH51H is an ancestor of a plant does not provide sufficient description of all of the morphological and physiological traits of that plant. Furthermore, the specification does not describe any molecular determinants that one would need to identify any genetic material as having been derived from PH51H or to verify that PH51H is within its pedigree. No description has been provided concerning molecular markers that are unique to the PH51H genome. Furtherstill, Applicant believes that it is technically impossible to sequence the entire genome of a specific variety.

Applicant emphasizes that the influence of PH51H cannot be removed from progeny that are 2 outcrosses removed from PH51H, and the claimed progeny cannot be derived without the use of PH51H as a parent. Applicant believes that this highlights the different perspective regarding claim scope between the Examiner and Applicant. Applicant contends that the Examiner's interpretation of the claims to progeny, as being of great breadth because a large number of plants could fall within its scope, ignores the essential limitation that only a plant developed through the use of PH51H is within the scope of the claim (response, page 13, 1st paragraph). However, the influence of the other ancestors of the claimed progeny plants also cannot be ignored. No description is provided at all as to the other ancestors, or the traits expressed by the progeny that are not expressed by PH51H. As PH51H is not the only ancestor of the progeny plants, the progeny necessarily express traits that are not expressed by PH51H. Yet, no description is provided at all concerning those traits. Applicant has argued that PH51H is unique, and that since PH51H is described, that its descendants must also be described. However, while the combination of genes that produce PH51H makes that line unique, Applicant does not provide any information as to why the genetic material itself is unique. For example, the specification does not describe why the genes that confer scatter grain resistance are different from those genes that confer the same resistance in other corn plants. The claimed progeny plants do not have the complete combination of genes that produce PH51H. Applicants here have not described the qualities of the genetic material of PH51H that make it unique, other than referring to the genome as a whole. As the claims are not limited to only self-crosses, all descendants do not inherit all of the genetic material of PH51H. Descendants also inherit genes from other ancestors.

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Applicant also argues, regarding claims drawn towards the deposited lines further comprising one or more transgenes or single gene conversions, that examples of traits and single gene conversions are given in the specification. Applicant argues that even if more than one trait is affected by the transgene, that the genetics of PH51H will only be minimally affected, and argue that insertion of one or a few genes into a genome that is estimated to have over 50,000 to 80,000 genes is a minor change (response, paragraph bridging pages 13-14). However, Applicant is not considering the effect of the transgene on the morphological and physiological traits of PH51H. Even the novice in the art would recognize that even a single gene could potentially have a significant effect on a plant. That the addition of a few more nucleotide sequences to the PH51H genome fails to significantly add to the total number of nucleotides, is not the point. Applicant also argues that claim 11 now indicates that the one or more transgenes confer a qualitative trait and that claim 30 indicates that the morphology and physiology of the maize plant comprising the transgene is substantially the same as PH51H (response, paragraph bridging pages 13-14). However, the amendments still do not describe the claimed plants, as they have traits that differ from PH51H. Further, it is not clear how to identify a plant that is “substantially the same” as PH51H from one that is different. In response to the suggestion made in the first Office action, that claims 11 and 30 be amended to list the types of transgenes contemplated, Applicant argues that such an amendment limits the scope to which Applicant is entitled, and believes that the molecular profile of such a transgenic plant would be substantially unchanged (response, paragraph bridging pages 13-14). However, the molecular profile of PH51H is not described in the specification.

Regarding claims 12, 13, 31, and 32: Applicants argue that the method claims of 12 and 31 are described, that one of ordinary skill in the art would know if they were using PH51H or PH6W further containing a transgene to develop a hybrid, that the hybrid has a genome with one set of the alleles from each inbred, and that the plant of claim 13 would have the genetic profile of PH51H except for the transgene (response, paragraph bridging pages 14-15). However, as PH6W plants further comprising a transgene are not described, methods that utilize them are not described, either. Further, the plants of claims 13 and 32 would also inherit half of its alleles from the other parent (which is not limited to be an inbred), which are not described.

Regarding claims 37-39, Applicant argues that the claims merely claim the method of searching for inbred PH51H seed within a bag of hybrid seed (response, page 15, 1st full paragraph). However, as the hybrids used in the method are not described, the method cannot be fully described either.

Finally, Applicant argues that one of ordinary skill would know how to cross PH51H do develop an F1 hybrid and also how to self plants derived from crosses. Applicant cites *Ex parte Parks* for indicating that it is sufficient if the originally filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed, and *J.E.M. Ag. Supply*, in which the Supreme Court stated that a breeder can use a plant that is protected by a PVP certificate to “develop” a new inbred line while he cannot use a plant patented under 101 for such a purpose (response, paragraph bridging pages 15-16). However, the concept of what is claimed is not clear, as the morphological and physiological traits expressed by the claimed progeny plants are not described. Further, that a breeder can use a plant

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protected by a PVP certificate, or deposited with the ATCC, is not the issue. The use of the deposited line does not provide a description of the claimed progeny plants.

Claim Rejections - 35 USC § 102 & 103

7. Claims 14, 17, 33, 36, 41, and 43 remain and claims 9, 10, 22, 28, 29, and 32 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35U.S.C. 103(a) as obvious over Piper (U.S. Patent No. 6,188,001), for the reasons of record stated in the Office action mailed 26 August 2002 under item 12. Applicant traverses in the paper filed 13 December 2002. Applicant's arguments were fully considered but were not found persuasive.

Applicant argues that the claimed progeny plants of claims 36 and 41 are limited to plants that are one cross away from PH51H, and are limited by the use of PH51H in the initial cross. Applicants argue that one would not be able to obtain plants within one cross of PH51H through modification of PH1W0 because PH51H comprises a unique and nonobvious combination of genetics (response, page 19, 3rd full paragraph). However, not all of the claimed progeny plants are limited to be within one cross of PH51H. For example, the plant of claim 14 is not limited to any generation. Hybrids produced from PH1W0 express two traits that are listed in claim 14. PH51H has only been described by phenotypic characteristics and not by genotype. While the combination of genes in the genome of PH51H may be unique, the specification does not teach that any particular gene is unique. Further, no molecular markers are taught that are unique to the PH51H genome, so one cannot determine the differences in the instantly claimed progeny plants from those of the prior art based on an analysis of the genome. A prior art plant having the same characteristics as the instantly claimed plant would anticipate the claimed plant even if

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it is made by a different method (i.e. different parent plants), and in the present case, only one of the claims places any kind of limitation on the characteristics that can be expressed. Further, the inbred taught by the reference is encompassed by the scope of claim 43, as the traits expressed by the claimed inbred are unknown. The inbred taught by Piper anticipates the instantly claimed inbred, as their properties do not distinguish each other. As the rejected claims do not place any limitations on the properties of the claimed progeny plants and seeds (except for claim 14), the Examiner does not have sufficient facts to determine whether the progeny plants and seeds are inherently the same. The Examiner cannot conclude that the claimed subject matter would have been obvious since it cannot be determined whether the plants differ from teachings of the reference. Where the prior art product seems to be identical, except that the prior art is silent as to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 UPSQ 430, 433 (CCPA 1977).

Applicant also submits the declaration of Dr. Stephen Smith, an employee of the assignee of the instant application, as evidence that the claimed progeny plants retain unique and non-obvious combinations of genetics derived from PH51H (response, Appendix D). The declaration indicates that SSR data markers were compared between PH51H and PH1W0. Of 161 SSR markers examined between the two plants, 26 showed differences. Of these, 13 were greater than 50 cM in distance and would not segregate together (declaration, item 3). However, the declaration does not describe the markers that are found in PH51H and the descendants derived therefrom. The declaration does not teach which, if any, of these markers are associated with the traits listed in claim 14. The declaration also indicates that it is extremely unlikely that a PH51H

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progeny, after one cycle of breeding, would be the same as PH1W0, and that it is unrealistic to assume that the only differences between PH51H and PH1W0 are the 26 markers is unrealistic (items 4 and 5). However, the instant claims directed to plant PH51H and its parts, have been withdrawn from the rejection. The declaration also indicates that the current maize genetic map contains sixty 50 cM units, which represents the maximum number of segregating loci, and, that these assumptions overestimate the odds of breeding PH1W0 from PH51H (item 5). However, as discussed above, there are no limits on the characteristics that the inbred of claim 43 can express, and without a description of the unique markers present in PH51H, one cannot determine if the instantly claimed inbreds can only be derived from PH51H.

Regarding claim 22: this claim is included because of the uncertainty of the recitation "essentially the same," as discussed above. Because of this recitation, plant PH1W0 can be considered to have essentially the same morphology and physiology of PH51H, and the reference teaches PH1W0 further having the trait of male sterility.

8. Claims 1-8, 21, 23-27, and 40 are allowed. Claims 9-20, 22, 28-39, 41-43, and 47-49 remain rejected.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy

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Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 70-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



ASHWIN D. MEHTA, PH.D
PATENT EXAMINER

February 25, 2003